

STATE OF SOUTH CAROLINA	)	
	)	IN THE COURT OF COMMON PLEAS
COUNTY OF ABBEVILLE	)	
	)	
Tracy Grant and William Grant,	)	Civil Action No.: 2021-CP-01- 00101
	)	
Plaintiffs,	)	
	)	
vs.	)	<b>SUMMONS</b>
	)	<b>JURY TRIAL REQUESTED</b>
Boston Scientific Corporation,	)	
	)	
Defendant.	)	
_____	)	

**TO THE ABOVE-NAMED DEFENDANT:**

**YOU ARE HEREBY SUMMONED** and required to answer the complaint herein, a copy of which is herewith served upon you, and to serve a copy of your answer to this complaint upon counsel for the plaintiffs, located at 1225 S. Church Street, Greenville, South Carolina 29605, within thirty (30) days after service hereof, exclusive of the day of such service, and if you fail to answer the complaint, judgment by default will be rendered against you for the relief demanded in the complaint.

**MOONEYHAM BERRY, LLC**

s/ Joe Mooneyham  
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*Attorney for Plaintiffs*

Greenville, South Carolina  
 April 22, 2021

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COUNTY OF ABBEVILLE	)	
Tracy Grant and William Grant,	)	Civil Action No.: 2021-CP-01- 00101
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Plaintiffs,	)	
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vs.	)	<b>COMPLAINT</b>
	)	<b>JURY TRIAL REQUESTED</b>
Boston Scientific Corporation,	)	
	)	
Defendant.	)	
_____	)	

The plaintiffs would hereby show this honorable Court that:

### PARTIES, JURISDICTION, AND VENUE

1. Tracy Grant (“Mrs. Grant”) and William Grant (“Mr. Grant”) are the plaintiffs in this matter and are citizens and residents of the County of Abbeville, in the State of South Carolina. Mr. and Mrs. Grant are husband and wife.

2. Defendant Boston Scientific Corporation (“BSC”) is a Delaware corporation doing business in South Carolina, and in Abbeville County. Boston Scientific Corporation was and is engaged in the business of designing, testing, inspecting, manufacturing, distributing, and selling medical products throughout the United States and particularly, in the state of South Carolina. Boston Scientific Corporation designed, tested, inspected, manufactured, distributed, and sold the *Advantage Fit Transvaginal Mid-Urethral Sling System* which is the subject of this action.

3. This Court has jurisdiction of the parties and subject matter of this action pursuant to S.C. Code, Ann., §36-2-803(1)(a),(b) and (h), the South Carolina “long arm statute.”

4. Venue is proper in this county pursuant to S.C. Code, Ann., §15-7-30.

**PLAINTIFFS' SPECIFIC FACTUAL BACKGROUND**

5. On October 21, 2016, Mrs. Grant presented to Self Regional Healthcare in Greenwood, South Carolina where Dr. Michael Gentry performed a total abdominal hysterectomy, bilateral salpingectomies, cystoscopy, and implantation of a *Boston Scientific Advantage Fit* mid-urethral transvaginal mesh sling (*Product Code UPN: M0068502110 Lot: ML00002313*), on Mrs. Grant. Mrs. Grant was discharged from Self Regional Healthcare on October 24, 2016.

6. On October 25, 2016, Mrs. Grant presented for a post-operative appointment with Dr. Gentry to evaluate her voiding status. On this visit, Dr. Gentry removed Mrs. Grant's catheter and told her that, "...she would be reevaluated in 48 hours and at that time if the sling needs tension adjustment we will perform that at that time otherwise we will check her postvoid residuals."

7. On October 26, 2016, Mrs. Grant went to the Emergency Room at Self Regional Healthcare complaining of abdominal pain and inflammation at the surgical site. She was diagnosed with intrinsic sphincter deficiency, polyp of corpus uteri, dysfunctional uterine bleeding, and abdominal surgical wound dehiscence. A follow-up appointment was scheduled with Dr. Gentry for the following day.

8. On October 27, 2016, Mrs. Grant followed up with Dr. Gentry and he addressed her open wound and stated in the medical records that, "She continues to have postop urinary retention she is voiding small amounts frequently post void residual catheterization today was performed and the patient had 3 cup capacity." Dr. Gentry goes on to say that, "...I was concerned that if I did try to stretch the sling then she would have significant incontinence."

9. On November 29, 2016, Mrs. Grant, again, followed up with Dr. Gentry and he referred her to the urogynecology department at Greenville Health System due to increased urine leakage and bladder frequency.

10. On February 27, 2017, Mrs. Grant underwent another operation to repair an incisional hernia and to remove the *Boston Scientific Advantage Fit* mid-urethral sling. Dr. Hema Brazell performed the mid-urethral sling removal. Dr. Brazell stated in her operative notes that, "The mid-urethral sling was noted to extremely distal and was ultimately located under the urethral meatus."

11. Following the removal of the *Boston Scientific Advantage Fit* mid-urethral sling, Mrs. Grant has continued to have issues with urgency, urinary incontinence, frequency, leakage, pain, and discomfort. Mrs. Grant had several post-operative appointments with Dr. Brazell and continuously stated her complaints to the doctor regarding the need to frequently self-catheterize and the embarrassment and pain this has caused her. Dr. Brazell prescribed Oxybutynin on May 25, 2017 and on July 24, 2017, Dr. Charis Chambers stated in her medical records that Mrs. Grant was not finding relief from Oxybutynin and was self-catheterizing every 2-3 hours and could not void on her own. Dr. Chambers discontinued the Oxybutynin and scheduled a urodynamic test to evaluate the cause of Mrs. Grant's voiding dysfunction.

12. On October 26, 2017, Dr. Brazell saw Mrs. Grant for another follow-up appointment and noted that Mrs. Grant had intravesical Botox for OAB and UUI on September 26, 2017. Dr. Brazell's notes indicated that Mrs. Grant told her that she does not think the Botox helped at all and that she is still suffering from extreme UUI and had been wearing pads to absorb the leakage. Mrs. Grant told Dr. Brazell that this has caused her great embarrassment and depression. Dr. Brazell stated, "Scar tissue from her sling surgery is

probably cause of her inability to empty, especially since she was fine w/regards to urinary emptying prior to sling placement. Will try Elavil to see if could possibly be from pelvic floor spasm.”

13. After the sling removal procedure, Mrs. Grant was told by medical staff that it could take over a year to return to normal urinary function. Mrs. Grant’s doctors also told her on numerous occasions that scar tissue was the cause of her dysfunction. Therefore, Mrs. Grant was not aware the *Advantage Fit* mid-urethral sling was the cause of her continued incontinence at the time. Even after multiple attempts made by the doctors to try to correct Mrs. Grant’s urinary incontinency and dysfunctions, Mrs. Grant continues to have severe complications related to the implantation and removal of the *Advantage Fit* mid-urethral sling.

14. As a direct and proximate cause resulting from the implantation of the *Boston Scientific Advantage Fit* mid-urethral sling by Dr. Gentry, Mrs. Grant has incurred medical expenses, lost wages and the opportunity for additional future income, has endured physical pain, has been emotionally damaged, has suffered temporary and permanent impairment of function, loss of consortium, and has lost enjoyment of life.

#### **FACTUAL BACKGROUND ON THE BOSTON SCIENTIFIC ADVANTAGE FIT TRANSVAGINAL SLING**

15. The plaintiffs repeat the allegations of the preceding paragraphs of their complaint as if repeated here verbatim.

16. BSC’s Advantage Fit sling contains monofilament polypropylene mesh. Polypropylene mesh has been used in surgery for more than fifty years. However, despite claims that polypropylene is inert, the scientific evidence shows that this material is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with BSC’s products. This negative response promotes inflammation

of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Furthermore, according to the expert opinion and testimony of Bruce A. Rosenzweig, M.D. in the MDL #2327, polypropylene "...degrades over time, causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, deformation, roping, rolling and curling of the mesh" *In re Ethicon, Inc.*, No.2:12-CV-09972 (2014).

17. On March 27, 2013, the FDA updated the Urogynecologic Surgical Mesh Implant website to include more information for patients about stress urinary incontinence (SUI). This update included the FDA's thinking about the use of surgical mesh for repair of SUI based on its analysis of adverse events reported to the FDA and findings reported in the scientific literature received from the September 9, 2011 meeting of the Obstetrics and Gynecology Devices Panel of the Medical Device Advisory Committee.

18. On January 6, 2017, the FDA issued the final order reclassifying instrumentation for use with urogynecology surgical mesh from class II to class III, requiring submission of 510(k)s for these devices.

**FOR A FIRST CAUSE OF ACTION**  
**(NEGLIGENCE)**

19. The plaintiffs repeat the allegations of the preceding paragraphs of their complaint as if repeated here verbatim.

20. Defendant BSC had a legal duty to individuals, including Mrs. Grant, to use reasonable care in designing, inspecting, testing, manufacturing, labeling, packaging and selling its products to avoid an unreasonable risk of physical harm to individuals.

21. Defendant BSC's breach of these duties constitutes negligence in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and selling its products.

22. Defendant BSC also negligently failed to warn or instruct Mrs. Grant and/or her health care providers of the subjects including, but not limited to, the following:

- a. The hazards associated with the product;
- b. The product's defects;
- c. The need for corrective or revision surgery;
- d. The severity of complications that could arise as a result of implantation of the product;
- e. Treatment of stress urinary incontinence with the product is no more effective than feasible available alternatives and exposes patients to greater risks; and
- f. Removal of the product due to complications may involve multiple surgeries and significantly impair the patient's quality of life.

23. As a direct and proximate result of BSC's negligence, Mrs. Grant has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will most likely undergo further medical treatment and/or procedures, has suffered financial or economic loss including lost wages, medical expenses, loss of consortium, and other damages.

24. The plaintiffs demand judgment against BSC for actual and punitive damages and such further relief as the Court deems just and proper.

**FOR A SECOND CAUSE OF ACTION**  
**(PRODUCT LIABILITY: DESIGN DEFECT)**

25. The plaintiffs repeat the allegations of the preceding paragraphs of their complaint as if repeated here verbatim.

26. The plaintiffs allege that the Advantage Fit mid-urethral sling was in a defective condition, and made unreasonably dangerous thereby, at the time it failed, causing Mrs. Grant continued injuries. The product was not reasonably safe for its intended use and was defective as described herein.

27. The product's defects include, but are not limited to, the following:

- a. the use of polypropylene material in the product and the immune reaction that results from such material, causing adverse reactions and injuries;
- b. The design of the product to be inserted through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and tissue breakdown and adverse reactions and injuries;
- c. The propensity of the product to shrink inside the body, which causes surrounding tissue to become inflamed, resulting in injuries;
- d. The use and design of arms and anchors in the product, which, when placed in women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;
- e. The propensity of the product becoming degraded or fragmented over time, which causes a chronic inflammatory reaction, and results in continuing injuries; and
- f. The inelasticity of the product, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain during normal activities that involve the pelvis (e.g. intercourse, defecation).



28. As a direct and proximate cause of BSC's Advantage Fit mid-urethral sling's defects, Mrs. Grant has experienced significant injuries, mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will most likely undergo further medical treatment and/or procedures, has suffered financial or economic loss including lost wages, medical expenses, loss of consortium, and other damages.

29. BSC is strictly liable to the plaintiffs for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

30. The plaintiffs demand judgment against BSC for actual damages and such further relief as the Court deems just and proper.

**FOR A THIRD CAUSE OF ACTION**  
**(PRODUCT LIABILITY: MANUFACTURING DEFECT)**

31. The plaintiffs repeat the allegations of the preceding paragraphs of their complaint as if repeated here verbatim.

32. The Advantage Fit mid-urethral sling implanted in Mrs. Grant was not reasonably safe for its intended use and was defective as described herein as a matter of law with respect to its manufacture, in that it deviated materially from BSC's design and manufacturing specifications in such a way as to pose unreasonable risks of serious bodily harm to Mrs. Grant.

33. As a direct and proximate result of BSC's defects, Mrs. Grant has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will most likely undergo further medical treatment and/or procedures, has suffered financial or economic loss including lost wages, medical expenses, loss of consortium, and other damages.

34. BSC is strictly liable to the plaintiffs for designing, manufacturing, marketing, labeling, packaging, and selling a defective product.

35. The plaintiffs demand judgment against BSC for actual damages and such further relief as the Court deems just and proper.

**FOURTH CAUSE OF ACTION**  
**(PRODUCT LIABILITY: FAILURE TO WARN)**

36. The plaintiffs repeat the allegations of the preceding paragraphs of their complaint as if repeated here verbatim.

37. The Advantage Fit mid-urethral sling implanted in Mrs. Grant was not reasonably safe for its intended use and was defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically, BSC did not provide sufficient or adequate warnings regarding:

- a. The product's propensities to contract, retract, and/or shrink inside the body;
- b. The product's propensities for degradation, fragmentation, and disintegration;
- c. The rate and manner of mesh erosion or extrusion;
- d. The risk of chronic inflammation resulting from the product;
- e. The risk of permanent vaginal or pelvic scarring as a result of the product;
- f. The risk of recurrent pelvic pain and other pain resulting from the product;
- g. The need for corrective or revision surgery to adjust or remove the product;
- h. The severity of complications that could arise as a result of implantation of the product;
- i. The hazards associated with the product;
- j. The product's defects described herein;

- k. Removal of the product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and
- l. Complete removal of the product may not be possible and may not result in complete resolution of the complications, including pain.

38. As a direct and proximate result of BSC's defects, Mrs. Grant has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will most likely undergo further medical treatment and/or procedures, has suffered financial or economic loss including lost wages, medical expenses, loss of consortium, and other damages.

39. BSC is strictly liable to the plaintiffs for designing, manufacturing, marketing, labeling, packaging, and selling a defective product.

40. The plaintiffs demand judgment against BSC for actual damages and such further relief as the Court deems just and proper.

**FIFTH CAUSE OF ACTION**  
**(BREACH OF EXPRESS WARRANTY)**

41. The plaintiffs repeat the allegations of the preceding paragraphs of their complaint as if repeated here verbatim.

42. Mrs. Grant alleges that at the time of surgical implantation, and continuing, BSC made assurances as described herein to the general public, hospitals, and health care professionals and thereby expressly warranted the safety and efficacy of the *Advantage Fit* mid-urethral sling, by its use of advertisements and the like, and moreover, did expressly warrant that the product was safe and reasonably fit for the use to which it was intended.

43. Mrs. Grant and/or her healthcare provider chose the product based upon BSC's warranties and representations as described herein regarding the safety and fitness of the product.

44. Mrs. Grant, individually and/or by and through her physician, reasonably relied upon BSC's express warranties and guarantees that the product was safe, merchantable, and reasonably fit for its intended purposes.

45. BSC breached these express warranties because the product implanted in Mrs. Grant was unreasonably dangerous and defective as described herein and not as BSC had represented.

46. BSC's breach of its express warranties resulted in the implantation of an unreasonable dangerous and defective product in the body of Mrs. Grant, placing her health and safety in jeopardy.

47. As a direct and proximate result of BSC's breach of the aforementioned express warranties, Mrs. Grant has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will most likely undergo further medical treatment and/or procedures, has suffered financial or economic loss including lost wages, medical expenses, loss of consortium, and other damages.

48. The plaintiffs allege BSC is liable to them pursuant to S.C. Code Ann., §36-2-313, for actual damages for its breach of express warranty.

**SIXTH CAUSE OF ACTION**  
**(BREACH OF IMPLIED WARRANTY)**

49. The plaintiffs repeat the allegations of the preceding paragraphs of their complaint as if repeated here verbatim.

50. BSC impliedly warranted that the *Advantage Fit* mid-urethral sling was merchantable and fit for the ordinary purposes for which it was intended.

51. The plaintiffs allege that at the time the product was implanted in Mrs. Grant to treat her stress urinary incontinence, the product was being used for the ordinary purposes for which it was intended. Furthermore, BSC was responsible for the designing, manufacturing, marketing, labeling, packaging, and selling of the product in question as contemplated by S.C. Code Ann., §36-2-314.

52. The plaintiffs allege that the unmerchantable condition of the *Advantage Fit* mid-urethral sling constituted a breach of the implied warranty of merchantability because the product implanted in Mrs. Grant was neither merchantable nor suited for its intended uses as warranted by BSC.

53. BSC's breach of its implied warranties resulted in the implantation of an unreasonable dangerous and defective product in the body of Mrs. Grant, placing Mrs. Grant's health and safety in jeopardy.

54. As a direct and proximate result of BSC's breach of the aforementioned implied warranties, Mrs. Grant has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will most likely undergo further medical treatment and/or procedures, has suffered financial or economic loss including lost wages, medical expenses, loss of consortium, and other damages.

55. The plaintiffs allege BSC is liable to them pursuant to S.C. Code Ann., §36-2-313, for actual damages for their breach of implied warranty.

56. The plaintiffs demand judgment against BSC for actual damages and such further relief as the Court deems just and proper.

**SEVENTH CAUSE OF ACTION**  
**(LOSS OF CONSORTIUM ON BEHALF OF WILLIAM GRANT)**

57. The plaintiffs repeat the allegations of the preceding paragraphs of their complaint as if repeated here verbatim.

58. As set forth above, the plaintiffs allege that at the time and place in question, they were husband and wife.

59. As set forth in more detail above, the plaintiffs allege that BSC is strictly liable for the injuries suffered by Ms. Grant; that BSC was negligent in designing, inspecting, testing, manufacturing, labeling, packaging and selling the product that injured her, and that BSC breached various warranties in the sale and distribution of the sling that is the subject of this action.

60. As set forth above, Mrs. Grant was severely injured as a proximate result of BSC's acts and omissions.

61. As a direct and proximate result of Mrs. Grant's injuries, Mr. Grant lost the benefit of her comfort and society, and suffered loss of consortium.

62. The plaintiffs are therefore informed and believe that he is entitled to judgment against BSC for actual and punitive damages for loss of consortium.

**WHEREFORE**, the plaintiffs demand judgment against the defendant, BSC, on each of their causes of action as follows:

- a) Compensatory or actual damages to the plaintiffs for past and future damages, including but not limited to pain and suffering, health care costs, medical monitoring, lost wages, loss of consortium, and loss of function, together with interest and costs as provided by law;
- b) Punitive and/or exemplary damages in an amount sufficient to punish the defendant and deter future similar conduct;

- c) The costs of these proceedings;
- d) Such other further relief as this Court deems just and proper.

**JURY DEMAND**

Pursuant to Rule 38(b) of the South Carolina Rules of Civil Procedure, the plaintiffs, by their undersigned attorney, demand a jury trial on all issues set forth in this cause as the Court deems just and proper.

Respectfully submitted,

**MOONEYHAM BERRY, LLC**

s/ Joe Mooneyham

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